

February 2, 1999

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 99-06

SUBJECT: Supplementary Aids for Applicants

TO: Applicants for Veterinary Biologics Licenses and  
for Permits for Distribution and Sale

The enclosed licensing package contains copies of the following:

1. The Virus-Serum-Toxin Act, as amended;
2. Veterinary Services Memorandum No. 800.50, Basic License Requirements for Applicants;
3. Veterinary Biologics Memorandum No. 800.84, Guidelines for Submission of Materials in Support of Licensure;
4. Veterinary Biologics General Licensing Consideration No. 800.200, Efficacy Studies;
5. Veterinary Biologics General Licensing Consideration No. 800.201, Backpassage Studies.
6. Forms used for regulatory purposes in the Biologics Program (APHIS Forms 2001, 2003, 2005, 2007, 2008, 2008A, 2015, and 2020); and
7. Veterinary Biological Products, a publication listing all USDA licensed manufacturers, permittees, and products.

Current copies of Title 9, Code of Federal Regulations, Parts 1-199, may be obtained from the Government Printing Office by writing to: Superintendent of Documents, Government Printing Office, Washington, DC 20402. The cost is \$40. The telephone number for telephone orders is Area Code (202) 512-1800, and the Internet address is [www.access.gpo.gov/sv\\_docs/sale.html](http://www.access.gpo.gov/sv_docs/sale.html).

Additional procedural and interpretive directives, forms, and more specific instructions for preparing and submitting the applications and supporting documents are available upon request from Licensing and Policy Development, Center for Veterinary Biologics.

In order to expedite the handling of your license or permit application, please contact the Licensing and Policy Development staff before preparing submission. The address is: Dr. Richard E. Hill, Jr., Director, USDA, APHIS, Veterinary Services, Center for Veterinary Biologics, Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, Iowa 50010-8197. The telephone number is (515) 232-5785.

For on-line information, the Internet address is [www.aphis.usda.gov/vs/cvb](http://www.aphis.usda.gov/vs/cvb). This site provides access to other pertinent Center for Veterinary Biologics program information. Also available at the Licensing and Policy Development site is an electronic mailing list; if you sign up, you will automatically receive new material as it is added to our web site.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.  
Director  
Center for Veterinary Biologics

7 Enclosures